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Registration Decision RD2014-01

3-decen-2-one

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Registration Decision for 3-decen-2-one

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of AMV-1018 Technical and AMV-1018 (98% Liquid Concentrate) for use on potatoes in storage to control sprouting once the dormancy period has ended.

Subsequent to the completion of the risk assessment for 3-decen-2-one the following name changes were made: the brand name for AMV-1018 Technical is now Smartblock 98% Technical, and the brand name for AMV-1018 (98% Liquid Concentrate) is now Smartblock.

An evaluation of available scientific information found that, under the approved conditions of use, the products have value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2013-12, *3-decen-2-one*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for 3-decen-2-one and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2013-12. This decision is consistent with the proposed registration decision stated in PRD2013-12.

For more details on the information presented in this Registration Decision, please refer to PRD2013-12, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is 3-decen-2-one?

3-decen-2-one is a plant growth regulator that belongs to the chemical family of the alpha-beta unsaturated aliphatic ketones. AMV-1018 (98% Liquid Concentrate), containing 98% 3-decen-2-one, is applied as an aerosol to potatoes in storage once there is evidence of sprouting. While the mode of action is not fully understood, 3-decen-2-one acts to damage or destroy the meristematic tissue of sprouts and actively growing terminal and axillary buds.

Health Considerations

Can Approved Uses of 3-decen-2-one Affect Human Health?

3-decen-2-one is unlikely to affect human health when it is used according to label directions.

Exposure to 3-decen-2-one may occur when handling the end-use product, AMV-1018 (98% Liquid Concentrate), which has a proposed commercial use as a sprout inhibitor for potatoes in commercial storage. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, 3-decen-2-one, is of low acute toxicity by the oral and dermal routes, and is slightly acutely toxic by the inhalation route. It is mildly irritating to the eyes, severely irritating to the skin, and is not a dermal sensitizer. It is considered to be non-mutagenic, and not a reproductive toxicant. Cautionary statements alerting users to the potential for respiratory toxicity and eye and skin irritation are required on product labels.

Dermal and inhalation exposure is possible for workers handling the end-use product, AMV-1018 (98% Liquid Concentrate), and for workers engaged in post-application clean-up and maintenance activities. Therefore, personal protective equipment and other risk-reduction measures are required on the end-use product label to mitigate such exposure concerns. Entry will not be allowed into treated areas prior to complete ventilation of the potato storage facility. The potential for bystander exposure is expected to be minimal as non-workers are prohibited from entering potato storage facilities during treatment.

Waivers and additional information obtained from the public domain were deemed adequate to address the potential for short-term toxicity.

Residues in Water and Food

Dietary risks from food and water are not of concern.

3-decen-2-one is used as an additive to flavour certain foods and it also occurs naturally in certain foods. The end-use product, AMV-1018 (98% Liquid Concentrate), will be applied as a fog directly to potatoes; however, food residue exposure is not expected to be of concern as exposure estimates indicate that use of AMV-1018 (98% Liquid Concentrate) will not appreciably increase the dietary exposure to 3-decen-2-one above what is currently expected from its presence in food. In addition, as the end-use product is to be applied inside a closed potato storage facility, exposure to 3-decen-2-one in drinking water is not expected to occur. The PMRA has also determined that a maximum residue limit (MRL) is not required for 3-decen-2-one.

Occupational Risks From Handling AMV-1018 (98% Liquid Concentrate)

Occupational risks are not of concern when AMV-1018 (98% Liquid Concentrate) is used according to label directions, which include protective measures.

Occupational exposure to individuals handling AMV-1018 (98% Liquid Concentrate) is not expected to result in unacceptable risk when the product is used according to label directions.

Precautionary and hygiene statements on the label (for example, wearing of personal protective equipment) are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When 3-decen-2-one Is Introduced Into the Environment?

3-decen-2-one is a chemical substance that occurs naturally in some food and is currently used as a flavouring agent in food industry. 3-decen-2-one is highly volatile and has a high solubility in water. It is expected to degrade rapidly in the environment through photochemical reactions (with hydroxyl radicals) or microbial activity. Environmental exposure from the indoor use of this product is expected to be limited.

There is no concern about inhalation risk to wild birds nesting or roosting in the vicinity of storage facilities. No or very limited exposure of aquatic ecosystem is expected.

Value Considerations

What Is the Value of AMV-1018 (98% Liquid Concentrate)?

AMV-1018 (98% Liquid Concentrate) is applied to potatoes in storage to control sprouting once the dormancy period has ended thereby extending the storage period. AMV-1018 (98% Liquid Concentrate) is an alternative option with a different mode of action to products containing chlorpropham, which are commonly used to extend the dormancy period of potatoes thereby delaying sprouting. The active ingredient, 3-decen-2-one, is classified as a biopesticide by the United States Environmental Protection Agency and is acceptable for use by the United States Food and Drug Administration as a food additive (flavouring agent), and has a Generally Recognized as Safe designation.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of AMV-1018 (98% Liquid Concentrate) to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The signal words "CAUTION – POISON, EYE IRRITANT", and "DANGER – SKIN IRRITANT" are required on the principal display panels of both the technical and end-use product labels. The statements "Harmful if inhaled", "May irritate eyes", and "Severely irritating to skin" are required on the secondary display panel of the technical and end-use product labels.

The personal protective equipment for all loading, handling, clean-up and maintenance activities required on the end-use product label includes a long-sleeved shirt, long pants, shoes, socks, respirator with a NIOSH/MSHA approved organic vapour-removing cartridge with a pre-filter approved for pesticides, goggles, and chemical resistant gloves. Storage areas must be ventilated for at least 24 hours or until ventilation is complete before allowing workers to enter for normal activities. If entering storage area before full ventilation, workers must wear coveralls over long-sleeved shirt, long pants, shoes, socks, chemical resistant gloves, and a self-contained breathing apparatus or full-face respirator with a NIOSH/MSHA approved organic vapour-removing cartridge with a pre-filter approved for pesticides.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2013-12) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

5 As per subsection 35(1) of the *Pest Control Products Act*.